



# Preventive Controls for Human Food Rule

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FOOD SAFETY MODERNIZATION ACT (FSMA)

# FDA Food Safety Modernization Act (FSMA)

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The FDA Food Safety Modernization Act (FSMA), the most sweeping reform of our food safety laws in more than 70 years, was signed into law by President Obama on **January 4, 2011**. It aims to ensure that the U.S. food supply is safe by shifting the focus from responding to contamination to **preventing** it.



# FSMA Includes 7 Final Rules

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1. **Preventive Controls for Human Food**
2. Preventive Controls for Animal Food
3. Intentional Adulteration
4. Foreign Supplier Verification
5. Third-Party Certification
6. Sanitary Transportation of Human and Animal Food
7. Produce Safety



# Preventive Controls for Human Food

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- The full title of the rule is the *Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Foods*. It is referred to as the **Preventive Controls for Human Food Rule**.
- The Rule sets forth new requirements and updates existing requirements for **facilities that manufacture, process, pack, or hold human food**.
- The Rule was published January 16, 2013 and became final in **September 2015**.

NYS Dept. of Agriculture & Markets has adopted all of the Rule's Subparts except Subpart E. Only the FDA will determine the circumstances where a facility may be withdrawn from a qualified facility exemption.

# Contents

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1. Subpart A – General Provisions
2. Subpart B – Current Good Manufacturing Practice
3. Subpart C – Hazard Analysis and Risk-Based Preventive Controls
4. Subpart D – Modified Requirements
5. *Subpart E – Withdrawal of a Qualified Facility Exemption*
6. Subpart F – Requirements Applying to Records that Must be Established and Maintained
7. Subpart G – Supply-Chain Program

# Major Features

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The Rule has two major features:

1. New provisions requiring hazard analysis and risk-based preventive controls that are more rigorous than HACCP.
  - Creation of a **written food safety plan**.
2. Revision of existing Good Manufacturing Practices (**cGMPs**).
  - **21 CFR Part 110** revised to **21 CFR Part 117**.

# HACCP vs. FSMA

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## HACCP

- Built on a foundation of GMP's and prerequisite programs
- Focuses on specific Process Control Steps
- Hazard Analysis
- HACCP Plan – All Critical Control Points (CCP's) have critical limits
- Monitoring, Corrective Actions, Verification, Record Keeping
- What you will do

## Preventive Controls for Human Food

- Built on a foundation of GMP's (updated) and prerequisite programs
- Includes other elements in addition to Process Control Steps
- Hazard Analysis – Includes *radiological hazards*
- **Food Safety Plan** – Not all preventive controls have critical limits
- Monitoring, Corrective Actions, Verification, Record Keeping
- How you will do it



# Written Food Safety Plan

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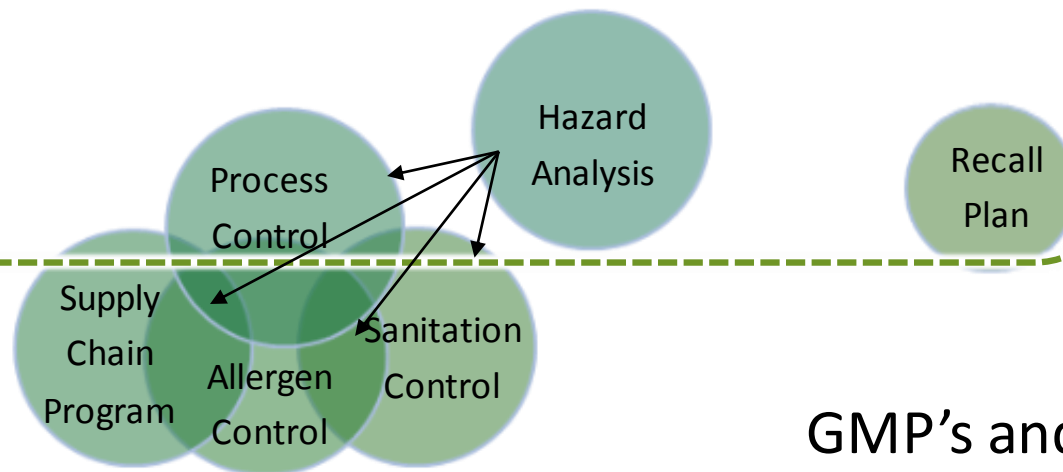
- A facility is required to maintain a **written food safety plan** and to keep **records** of each element of the plan.
- Only a **qualified individual**, either through training or experience, can write the facility's food safety plan.
  - *E.g.* Human Food Preventive Control Qualified Individual (**PCQI**) course.
- The food safety plan must be reassessed **every 3 years** or more frequently if there are problems.



# Overview of a Food Safety Plan

## Food Safety Plan

Includes procedures for monitoring, corrective actions, and verification.



GMP's and Other  
Prerequisite Programs

**21 CFR Part  
117, Subpart C,  
§117.126**

# Contents of a Food Safety Plan

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The written **food safety plan** must include:



# 1. Hazard Analysis

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The manufacturer must identify any **known** or **reasonably foreseeable** biological, chemical, and physical hazards, and determine if any of those hazards require a **preventive control**.



## 2. Preventive Controls

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If the hazard analysis identifies a hazard that requires a preventive control, the manufacturer is required to develop and implement a control to **significantly minimize** or **prevent** the hazard. These include:

- **Process controls**
- **Food allergen controls**
- **Sanitation controls**
- **Other controls**



## 2. Preventive Controls

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The manufacturer must also ensure that preventive controls are met using the following actions with subsequent **documentation**:

- **Monitoring**
- **Corrections**
- **Corrective Actions**
- **Verification**



# 3. Risk-Based Supply Chain Program

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If the manufacturer identifies a hazard related to an **ingredient** received from a supplier and depends on the supplier to control for that hazard, the manufacturer must implement a supply-chain program with appropriate **verification activities**:

- Using **approved suppliers**.
- Determining, conducting, and documenting appropriate **supplier verification activities**.
  - *E.g.* On-site audit, sampling and testing of raw material, review of suppliers' relevant food safety records.

## 4. Recall Plan

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If a hazard analysis identifies a hazard that requires a preventive control, the manufacturer must have a **written recall plan** that includes the procedures that describe the steps to perform the recall and at a minimum, assigns responsibility for:

- Notifying **direct consignees** of the food being recalled, including how to return or dispose of affected food.
- Notifying the **public** about hazards in the food.
- Conducting **effectiveness checks**.
- Appropriately **disposing** of recalled product.



# Current Good Manufacturing Practices

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The Rule updates **Good Manufacturing Practice (cGMP's)** requirements.

## Updates:

- All employees must receive **training** on the principles of food hygiene and food safety. **Records** must be maintained of training.
- Facilities are required to employ practices and procedures to control for **allergen cross-contact**.
- Provisions state specific holding and distributing guidelines for **human food by-products used for animal food**.

# Purpose of GMP's

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Good Manufacturing Practices provide guidance for manufacturing, testing, and quality assurance of food to ensure that the product is safe for consumption.

All GMP guidelines follow basic principles:

1. **Instructions** and procedures must be written in **clear** and **unambiguous** language.
2. **Records** produced during the manufacturing process (*e.g.* temperature controls, cleaning/sanitation schedules, training, batch, lot codes, etc.) must be **maintained**.

# Contents of cGMP's

**21 CFR Part  
117, Subpart B**

cGMP Category	cGMP Requirement:
§117.10 Personnel	<ol style="list-style-type: none"> <li>1. Disease control</li> <li>2. Cleanliness</li> </ol>
§117.20 Plant and Grounds	<ol style="list-style-type: none"> <li>1. Grounds</li> <li>2. Plant construction and design</li> </ol>
§117.35 Sanitary Operations	<ol style="list-style-type: none"> <li>1. General maintenance</li> <li>2. Substances used in cleaning and sanitizing; storage of toxic materials</li> <li>3. Pest control</li> <li>4. Sanitation of food-contact surfaces</li> <li>5. Sanitation of non-food-contact surfaces</li> <li>6. Storage and handling of cleaned portable equipment and utensils</li> </ol>
§117.37 Sanitary Facilities and Controls	<ol style="list-style-type: none"> <li>1. Water supply</li> <li>2. Plumbing</li> <li>3. Sewage disposal</li> <li>4. Toilet facilities</li> <li>5. Hand-washing facilities</li> <li>6. Rubbish and offal disposal</li> </ol>
§117.40 Equipment and Utensils	Design, construction, and maintenance of equipment and utensils.
§117.80 Processes and Controls	<ol style="list-style-type: none"> <li>1. General</li> <li>2. Raw materials and other ingredients</li> <li>3. Manufacturing operations</li> </ol>
§117.93 Warehousing and Distribution	Storage and transportation of final food product must protect against contamination and deterioration of the food and its container.
§117.95 Holding and Distribution of Human Food By-Products for Use as Animal Food ★	Human food by-products held for distribution as animal food without additional manufacturing/processing must be held under conditions that will protect against contamination. By-products must also be labeled.
§117.110 Defect Action Levels ★	The manufacturer/processor/packer/holder must at all times utilize quality control operations that reduce natural or unavoidable defects to the lowest level currently feasible. The mixing of a food containing defects at levels that render that food adulterated with another lot is not permitted.

# Personnel

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## 1. Disease Control



Any person who, by medical examination or supervisory observation, appears to have an **illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination** by which there is a reasonable possibility of food, food-contact surfaces, or food-packaging materials becoming contaminated, must be excluded from any operations which may be expected to result in such contamination until the condition is corrected, unless conditions such as open lesions, boils, and infected wounds are **adequately covered** (*e.g.* by an impermeable cover). **Personnel must be instructed to report such health conditions to their supervisors.**

# Personnel

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## 2. Cleanliness

All persons working in direct contact with food, food-contact surfaces, and food-packaging materials must conform to **hygienic practices** while on duty to the extent necessary to **protect against allergen cross-contact and against contamination** of food. The methods for maintaining cleanliness include:

- (1) **Wearing outer garments** suitable to the operation in a manner.
- (2) Maintaining adequate **personal cleanliness**.
- (3) **Washing hands** thoroughly (and sanitizing if necessary) in an **adequate hand-washing facility before starting work, after each absence from the work station, and at any other time when the hands may have become soiled or contaminated.**

# Personnel

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(4) **Removing all unsecured jewelry and other objects** that might fall into food, equipment, or containers, and **removing hand jewelry** that cannot be adequately sanitized during periods in which food is manipulated by hand. If such hand jewelry cannot be removed, it may be covered by material which can be maintained in an intact, clean, and sanitary condition and which effectively protects against the contamination by these objects of the food, food-contact surfaces, or food-packaging materials.

(5) **Maintaining gloves**, if they are used in food handling, in an intact, clean, and sanitary condition.

(6) Wearing, where appropriate, in an effective manner, **hair nets, headbands, caps, beard covers, or other effective hair restraints**.

# Personnel

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(7) **Storing clothing or other personal belongings** in areas other than where food is exposed or where equipment or utensils are washed.

(8) Confining the following to areas other than where food may be exposed or where equipment or utensils are washed: **eating food, chewing gum, drinking beverages, or using tobacco.**

(9) Taking any other necessary precautions to protect against allergen cross-contact and against contamination of food, food-contact surfaces, or food-packaging materials with microorganisms or foreign substances (including **perspiration, hair, cosmetics, tobacco, chemicals, and medicines applied to the skin**).





# Plant and Grounds

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## 1. Grounds

The grounds about a food plant under the control of the operator must be kept in a condition that will **protect against the contamination** of food. The methods for adequate maintenance of grounds must include:

- (1) **Properly storing equipment, removing litter and waste, and cutting weeds or grass** within the immediate vicinity of the plant that may constitute an attractant, breeding place, or harborage for pests.
- (2) **Maintaining roads, yards, and parking lots** so that they do not constitute a source of contamination in areas where food is exposed.
- (3) Adequately **draining areas** that may contribute contamination to food by seepage, foot-borne filth, or providing a breeding place for pests.

# Plant and Grounds

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(4) **Operating systems for waste treatment and disposal** in an adequate manner so that they do not constitute a source of contamination in areas where food is exposed.

(5) If the plant grounds are bordered by **grounds not under the operator's control and not maintained in the manner described** in paragraphs (a)(1) through (4) of this section, care must be exercised in the plant by inspection, extermination, or other means to exclude pests, dirt, and filth that may be a source of food contamination.

## 2. Plant construction and design

The plant must be suitable in **size, construction, and design** to facilitate maintenance and sanitary operations for food-production purposes. The plant must:

(1) Provide **adequate space for such placement of equipment and storage of materials** as is necessary for maintenance, sanitary operations, and the production of safe food.

# Plant Construction and Design

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(2) Permit the taking of adequate precautions to **reduce the potential for allergen cross-contact and for contamination** of food, food-contact surfaces, or food-packaging materials with microorganisms, chemicals, filth, and other extraneous material.

Precautions may highlight: **location, time, partition, air flow systems, dust control systems, enclosed systems**, or other effective means.

(3) Permit the taking of adequate precautions to protect food in **installed outdoor bulk vessels** by any effective means, including:

(i) Using **protective coverings**.

(ii) **Controlling areas over and around the vessels** to eliminate harborages for pests.

(iii) **Checking on a regular basis** for pests and pest infestation.

(iv) **Skimming fermentation vessels**, as necessary.

# Plant Construction and Design

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(4) Be constructed in such a manner that **floors, walls, and ceilings** may be adequately cleaned and kept clean and kept in good repair; that **drip or condensate from fixtures, ducts and pipes** does not contaminate food, food-contact surfaces, or food-packaging materials; and that **aisles or working spaces** are provided between equipment and walls and are adequately unobstructed and of adequate width to permit employees to perform their duties and to protect against contamination with clothing or personal contact.

(5) Provide **adequate lighting** in hand-washing areas, dressing and locker rooms, and toilet rooms and in all areas where food is examined, manufactured, processed, packed, or held and where equipment or utensils are cleaned; and provide **shatter-resistant light bulbs, fixtures, skylights, or other glass** suspended over exposed food in any step of preparation or otherwise protect against food contamination in case of glass breakage.

(6) Provide **adequate ventilation or control equipment** to minimize dust, odors and vapors (including steam and noxious fumes) in areas where they may cause **allergen cross-contact or contaminate** food; and locate and operate **fans** and other air-blowing equipment in a manner that **minimizes the potential for allergen cross-contact and for contaminating** food, food-packaging materials, and food-contact surfaces.

(7) Provide, where necessary, **adequate screening** or other protection against pests.

# Sanitary Operations

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## 1. General maintenance

Buildings, fixtures, and other physical facilities of the plant must be maintained in a clean and sanitary condition and must be kept in repair adequate to prevent food from becoming adulterated. Cleaning and sanitizing of utensils and equipment must be conducted in a manner that **protects against allergen cross-contact and against contamination** of food, food-contact surfaces, or food-packaging materials.



# Sanitary Operations

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## 2. Substances used in cleaning and sanitizing; storage of toxic materials

(1) Cleaning compounds and sanitizing agents used in cleaning and sanitizing procedures must be free from undesirable microorganisms and must be safe and adequate under the conditions of use.

Compliance with this requirement must be **verified** by any effective means, including **purchase of these substances under a letter of guarantee or certification or examination** of these substances for contamination. Only the following **toxic materials** may be used or stored in a plant where food is processed or exposed:

- (i) Those **required to maintain clean and sanitary conditions**;
- (ii) Those **necessary for use in laboratory testing procedures**;
- (iii) Those **necessary for plant and equipment maintenance and operation**; and
- (iv) Those **necessary for use in the plant's operations**.

(2) Toxic cleaning compounds, sanitizing agents, and pesticide chemicals must be **identified, held, and stored** in a manner that **protects against contamination** of food, food-contact surfaces, or food-packaging materials.

# Sanitary Operations

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## 3. Pest control

Pests must not be allowed in any area of a food plant. **Guard, guide, or pest-detecting dogs** may be allowed in some areas of a plant if the presence of the dogs is unlikely to result in contamination of food, food-contact surfaces, or food-packaging materials. Effective measures must be taken to exclude pests from the manufacturing, processing, packing, and holding areas and to **protect against the contamination** of food on the premises by pests. The use of **pesticides** to control pests in the plant is permitted only under precautions and restrictions that will **protect against the contamination** of food, food-contact surfaces, and food-packaging materials.





# Sanitary Operations

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## 4. Sanitation of food-contact surfaces

All food-contact surfaces, including utensils and food-contact surfaces of equipment, must be cleaned as frequently as necessary to **protect against allergen cross-contact and against contamination** of food.

(1) Food-contact surfaces used for manufacturing/processing, packing, or holding **low-moisture food** must be in a clean, dry, sanitary condition before use. When the surfaces are wet-cleaned, they must, when necessary, be sanitized and thoroughly dried before subsequent use.

(2) In **wet processing**, when cleaning is necessary to **protect against allergen cross-contact or the introduction of microorganisms** into food, all food-contact surfaces must be cleaned and sanitized before use and after any interruption during which the food-contact surfaces may have become contaminated. Where equipment and utensils are used in a **continuous production operation**, the utensils and food-contact surfaces of the equipment must be cleaned and sanitized as necessary.

(3) **Single-service articles** (such as utensils intended for one-time use, paper cups, and paper towels) must be stored, handled, and disposed of in a manner that **protects against allergen cross-contact and against contamination** of food, food-contact surfaces, or food-packaging materials.

# Sanitary Operations

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## 5. Sanitation of non-food-contact surfaces

Non-food-contact surfaces of equipment used in the operation of a food plant must be cleaned in a manner and as frequently as necessary to **protect against allergen cross-contact and against contamination** of food, food-contact surfaces, and food-packaging materials.

## 6. Storage and handling of cleaned portable equipment and utensils

Cleaned and sanitized portable equipment with food-contact surfaces and utensils must be stored in a location and manner that **protects food-contact surfaces from allergen cross-contact and from contamination**.



# Sanitary Facilities and Controls

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Each plant must be equipped with adequate sanitary facilities and accommodations including:

## 1. Water supply

The water supply must be adequate for the operations intended and must be derived from an adequate source. Any water that contacts food, food-contact surfaces, or food-packaging materials must be safe and of adequate sanitary quality. Running water at a suitable **temperature**, and under **pressure** as needed, must be provided in all areas where required for the processing of food, for the cleaning of equipment, utensils, and food-packaging materials, or for employee sanitary facilities.



# Sanitary Facilities and Controls

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**2. Plumbing.** Plumbing must be of adequate size and design and adequately installed and maintained to:

- (1) **Carry adequate quantities** of water to required locations throughout the plant.
- (2) Properly **convey sewage and liquid disposable waste** from the plant.
- (3) Avoid constituting a **source of contamination** to food, water supplies, equipment, or utensils or creating an unsanitary condition.
- (4) Provide adequate **floor drainage** in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor.
- (5) Provide that there is **not backflow** from, or **cross-connection** between, piping systems that discharge waste water or sewage and piping systems that carry water for food or food manufacturing.

# Sanitary Facilities and Controls

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**3. Sewage disposal.** Sewage must be disposed of into an adequate sewerage system or disposed of through other adequate means.

**4. Toilet facilities.** Each plant must provide employees with adequate, readily accessible toilet facilities. Toilet facilities must be kept clean and must not be a potential source of contamination of food, food-contact surfaces, or food-packaging materials.

**5. Hand-washing facilities.** Each plant must provide hand-washing facilities designed to ensure that an employee's hands are not a source of contamination of food, food-contact surfaces, or food-packaging materials, by providing facilities that are adequate, convenient, and furnish running water at a suitable temperature.

**6. Rubbish and offal disposal.** Rubbish and any offal must be so conveyed, stored, and disposed of as to minimize the development of odor, minimize the potential for the waste becoming an attractant and harborage or breeding place for pests, and protect against contamination of food, food-contact surfaces, food-packaging materials, water supplies, and ground surfaces.

# Equipment and Utensils

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(a)(1) All plant equipment and utensils used in manufacturing, processing, packing, or holding food must be so designed and of such material and workmanship as to be **adequately cleanable**, and must be **adequately maintained to protect against allergen cross-contact and contamination**.

(2) Equipment and utensils must be designed, constructed, and used appropriately to **avoid the adulteration of food with lubricants, fuel, metal fragments, contaminated water**, or any other contaminants.

(3) Equipment must be installed so as to **facilitate the cleaning and maintenance of the equipment and of adjacent spaces**.

(4) **Food-contact surfaces must be corrosion-resistant** when in contact with food.

(5) **Food-contact surfaces must be made of nontoxic materials** and designed to withstand the environment of their intended use and the action of food, and, if applicable, cleaning compounds, sanitizing agents, and cleaning procedures.

(6) **Food-contact surfaces must be maintained to protect food from allergen cross-contact and from being contaminated** by any source, including unlawful indirect food additives.

# Equipment and Utensils

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(b) **Seams on food-contact surfaces must be smoothly bonded or maintained** so as to minimize accumulation of food particles, dirt, and organic matter and thus minimize the opportunity for growth of microorganisms and **allergen cross-contact**.

(c) **Equipment** that is in areas where food is manufactured, processed, packed, or held and that **does not come into contact with food** must be so constructed that it can be kept in a clean and sanitary condition.

(d) **Holding, conveying, and manufacturing systems, including gravimetric, pneumatic, closed, and automated systems**, must be of a design and construction that enables them to be maintained in an appropriate clean and sanitary condition.

# Equipment and Utensils



(e) Each **freezer and cold storage compartment** used to store and hold food capable of supporting growth of microorganisms must be **fitted with an indicating thermometer, temperature-measuring device, or temperature-recording device** so installed as to show the temperature accurately within the compartment.

(f) **Instruments and controls** used for measuring, regulating, or recording temperatures, pH, acidity, water activity, or other conditions that control or prevent the growth of undesirable microorganisms in food must be accurate and precise and adequately maintained, and adequate in number for their designated uses.

(g) **Compressed air or other gases** mechanically introduced into food or used to clean food-contact surfaces or equipment must be treated in such a way that food is not contaminated with unlawful indirect food additives.



# Processes and Controls

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## 1. General

- (1) All operations in the **manufacturing, processing, packing, and holding** of food (including operations directed to **receiving, inspecting, transporting, and segregating**) must be conducted in accordance with adequate sanitation principles.
- (2) Appropriate **quality control operations** must be employed to ensure that food is suitable for human consumption and that food-packaging materials are **safe and suitable**.
- (3) Overall **sanitation** of the plant must be under the **supervision of one or more competent individuals** assigned responsibility for this function.
- (4) Adequate precautions must be taken to ensure that **production procedures do not contribute to allergen cross-contact and to contamination** from any source.

# Processes and Controls

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(5) **Chemical, microbial, or extraneous-material testing procedures** must be used where necessary to identify sanitation failures or possible **allergen cross-contact and food contamination**.

(6) All food that has become contaminated to the extent that it is **adulterated** must be **rejected**, or if appropriate, **treated** or processed to eliminate the contamination.

## 2. Raw materials and other ingredients

(1) Raw materials and other ingredients must be **inspected and segregated** or otherwise handled as necessary to ascertain that they are clean and suitable for processing into food and must be stored under conditions that will **protect against allergen cross-contact and against contamination and minimize deterioration**. Raw materials must be **washed or cleaned** as necessary to remove soil or other contamination. **Water** used for washing, rinsing, or conveying food must be safe and of adequate sanitary quality. Water may be reused for washing, rinsing, or conveying food if it does not cause **allergen cross-contact** or increase the level of contamination of the food.

# Processes and Controls

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(2) Raw materials and other ingredients must either not contain levels of microorganisms that may render the food injurious to the health of humans, or they must be **pasteurized or otherwise treated** during manufacturing operations so that they no longer contain levels that would cause the product to be adulterated.

(3) Raw materials and other ingredients susceptible to contamination with **aflatoxin or other natural toxins** must comply with **FDA regulations for poisonous or deleterious substances** before these raw materials or other ingredients are incorporated into finished food.

(4) Raw materials, other ingredients, and rework susceptible to contamination with **pests, undesirable microorganisms, or extraneous material** must comply with applicable **FDA regulations for natural or unavoidable defects** if a manufacturer wishes to use the materials in manufacturing food.

# Processes and Controls

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(5) Raw materials, other ingredients, and rework must be held in **bulk**, or in containers designed and constructed so as to **protect against allergen cross-contact and against contamination** and must be held at such temperature and relative humidity and in such a manner as to prevent the food from becoming adulterated. Material scheduled for **rework** must be identified as such.

(6) **Frozen** raw materials and other ingredients must be kept frozen. If **thawing** is required prior to use, it must be done in a manner that prevents the raw materials and other ingredients from becoming adulterated.

(7) **Liquid or dry raw materials** and other ingredients received and stored in bulk form must be held in a manner that **protects against allergen cross-contact and against contamination**.

(8) Raw materials and other ingredients that are **food allergens**, and rework that contains food allergens, must be identified and held in a manner that **prevents allergen cross-contact**.

# Processes and Controls

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## 3. Manufacturing operations

- (1) Equipment and utensils and food containers must be maintained in an adequate condition through **appropriate cleaning and sanitizing**, as necessary. Insofar as necessary, equipment must be **taken apart for thorough cleaning**.
- (2) All food manufacturing, processing, packing, and holding must be conducted under such conditions and controls as are necessary to **minimize the potential for the growth of microorganisms, allergen cross-contact, contamination of food, and deterioration of food**.
- (3) Food that can support the rapid growth of undesirable microorganisms must be held at **temperatures** that will prevent the food from becoming adulterated during manufacturing, processing, packing, and holding.
- (4) Measures such as **sterilizing, irradiating, pasteurizing, cooking, freezing, refrigerating, controlling pH, or controlling aw** that are taken to destroy or prevent the growth of undesirable microorganisms must be adequate under the conditions of manufacture, handling, and distribution to prevent food from being adulterated.

# Processes and Controls

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(5) **Work-in-process and rework** must be handled in a manner that **protects against allergen cross-contact, contamination, and growth of undesirable microorganisms**.

(6) Effective measures must be taken to **protect finished food from allergen cross-contact and from contamination** by raw materials, other ingredients, or refuse. When raw materials, other ingredients, or refuse are **unprotected**, they must **not** be handled simultaneously in a **receiving, loading, or shipping area** if that handling could result in **allergen cross-contact or contaminated food**. Food **transported by conveyor** must be **protected against allergen cross-contact and against contamination** as necessary.

(7) Equipment, containers, and utensils used to convey, hold, or store raw materials and other ingredients, work-in-process, rework, or other food must be constructed, handled, and maintained during manufacturing, processing, packing, and holding in a manner that **protects against allergen cross-contact and against contamination**.

(8) Adequate measures must be taken to **protect against the inclusion of metal or other extraneous material** in food.

# Processes and Controls

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(9) Food, raw materials, and other ingredients that are **adulterated**:

(i) Must be disposed of in a manner that **protects against the contamination** of other food; or

(ii) If the adulterated food is capable of being **reconditioned**, it must be:

(A) Reconditioned using a method that has been proven to be effective; or

(B) Reconditioned and reexamined and subsequently found not to be adulterated within the meaning of the **Federal Food, Drug, and Cosmetic Act** before being incorporated into other food.

(10) Steps such as **washing, peeling, trimming, cutting, sorting and inspecting, mashing, dewatering, cooling, shredding, extruding, drying, whipping, defatting, and forming** must be performed so as to **protect food against allergen cross-contact and against contamination**. Food must be protected from contaminants that may drip, drain, or be drawn into the food.

# Processes and Controls

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(11) **Heat blanching**, when required in the preparation of food capable of supporting microbial growth, must be effected by heating the food to the required temperature, holding it at this temperature for the required time, and then either rapidly cooling the food or passing it to subsequent manufacturing without delay. Growth and contamination by thermophilic microorganisms in blanchers must be minimized by the use of adequate operating temperatures and by periodic cleaning and sanitizing as necessary.

(12) **Batters, breading, sauces, gravies, dressings, dipping solutions**, and other similar preparations that are held and used repeatedly over time must be treated or maintained in such a manner that they are protected against allergen cross-contact and against contamination, and minimizing the potential for the growth of undesirable microorganisms.

(13) **Filling, assembling, packaging**, and other operations must be performed in such a way that the food is **protected against allergen cross-contact, contamination and growth of undesirable microorganisms**.



# Processes and Controls

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(14) Food, such as **dry mixes, nuts, intermediate moisture food, and dehydrated food**, that relies principally on the control of  $a_w$  for preventing the growth of undesirable microorganisms must be processed to and maintained at a safe moisture level.

(15) Food, such as **acid and acidified food**, that relies principally on the control of **pH** for preventing the growth of undesirable microorganisms must be monitored and maintained at a **pH of 4.6 or below**.

(16) When **ice** is used in contact with food, it must be made from water that is safe and of adequate sanitary quality in accordance with **117.37(a)**, and must be used only if it has been manufactured in accordance with **current good manufacturing practice** as outlined in this part.

# Warehousing and Distribution

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Storage and transportation of food must be under conditions that will **protect against allergen cross-contact** and against **biological, chemical (including radiological), and physical contamination** of food, as well as against **deterioration of the food and the container**.





# Holding and Distribution of Human Food By-Products for Use as Animal Food

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(a) Human food by-products held for distribution as animal food without additional manufacturing or processing by the human food processor must be held under conditions that will **protect against contamination**, including the following:

- (1) **Containers and equipment** used to convey or hold by-products before distribution must be designed, constructed of appropriate material, cleaned as necessary, and maintained to **protect against contamination**;
- (2) By-products held for distribution must be held in a way to protect against contamination from sources such as **trash**; and
- (3) During holding, by-products must be **accurately identified**.

(b) **Labeling** that identifies the by-product by the common or usual name must be affixed to or accompany by-products when distributed.

(c) **Shipping containers** (*e.g.* totes, drums, and tubs) and **bulk vehicles** used to distribute by-products must be examined prior to use to **protect against contamination** from the container or vehicle when the facility is responsible for transporting the by-products itself or arranges with a third party to transport the by-products.

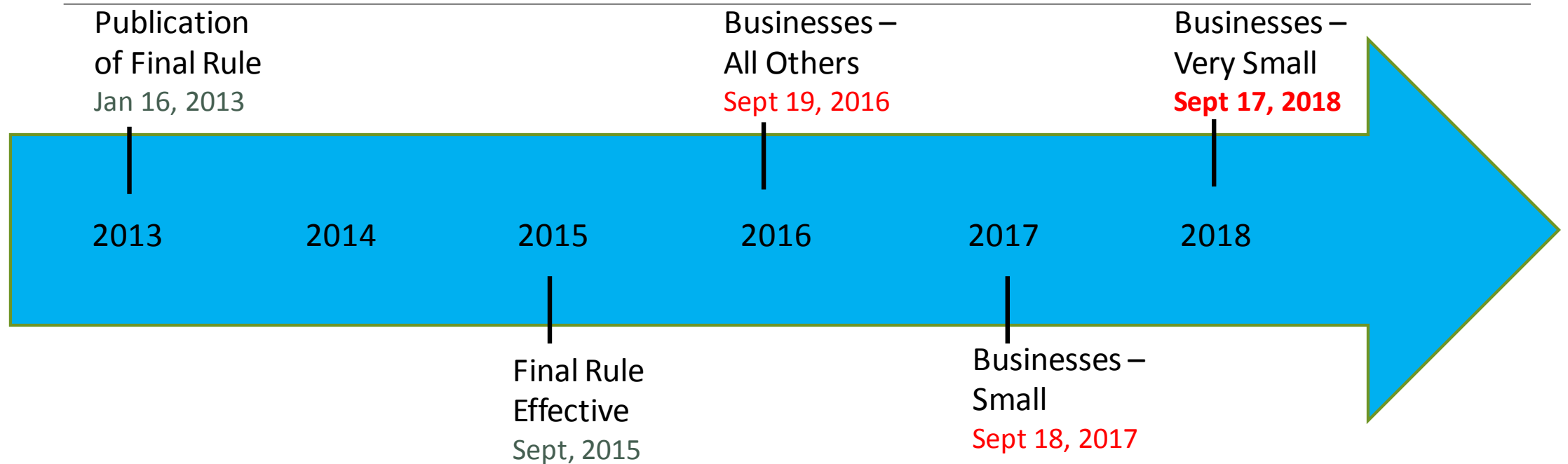


# Defect Action Levels

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- (a) The manufacturer, processor, packer, and holder of food must at all times utilize **quality control operations** that reduce natural or unavoidable defects to the lowest level currently feasible.
- (b) The mixing of a food containing **defects at levels that render that food adulterated** with another lot of food is not permitted and renders the final food adulterated, regardless of the defect level of the final food. For examples of defect action levels that may render food adulterated, see the **Defect Levels Handbook**, which is accessible at <http://www.fda.gov/pchfrule> and <http://www.fda.gov>.

# Compliance Timeline



All Others (Large) – **greater than 500** full-time equivalent employees

Small – **fewer than 500** full-time equivalent employees

Very Small – average **less than \$1 million** per year in annual sales of human food plus the market value of human food manufactured, processed, packed, or held without sale

# Qualified Exemption

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- **Qualified facilities** are not subject to **Subparts C and G**, but are subject to **modified requirements** {21 CFR Part 117.5(a)}.
- Facility is exempt if:
  - Defined as a **very small business** OR
  - The average annual monetary value of all food sold during the **last 3 years** was **less than \$500,000** AND sales to **qualified end-users** exceeds sales to others.

# Definitions

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- **Very small business**: a business averaging **less than \$1,000,000** per year during the **last 3 years** in **sales of human food PLUS the market value of human food manufactured, processed, packed, or held without sale.**
- **Qualified end-users**: consumer, local retailer or restaurant **within the same state or Native American reservation** or **within 275 miles** from the qualified facility and is purchasing the food for sale directly to consumers.

# Modified Requirements

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*Found in 21 CFR Part 117.201.*

- The qualified facility would be required to **notify FDA about its exemption status**, maintain its **20-C license** and comply with GMPs.
- The qualified facility is able to follow 21 CFR Part 110 GMPs until the **September 17, 2018 compliance date** when **Part 117 cGMPs** are enacted for all manufacturers.



# Other Exemptions

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*All exemptions can be found in **21 CFR Part 117.5**. (a) – (j) outlines facilities exempt from **Subparts C and G**. (k) outlines facilities exempt from **Subpart B**.*

- (b) Activities that are subject to **seafood HACCP** (part 123), (c) **juice HACCP** (part 120) and (d) **low-acid canned food** requirements (part 113).
- (e) Activities of a **dietary supplement** that are subject to the CGMP requirements of part 111.
- (f) Activities of a facility that are subject to **section 419 of the Food, Drug and Cosmetic Act** (Standards for Produce Safety).

# Other Exemptions

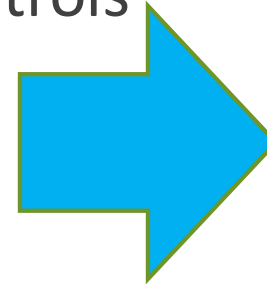
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- **(g)/(h) Small and very small** on-farm businesses conducting **low-risk activities**.
  - Low-risk activities include packing (or re-packing), sorting, culling or grading, and storing of: baked goods, candy; jams, jellies and preserves, etc.
- **(i) Alcoholic beverages** at a facility that obtained a permit, registered or obtained approval of a notice or application from the Secretary of the Treasury.
- **(j) Facilities solely engaged in storage of raw agricultural commodities (other than fruits and vegetables, RACs)** intended for further distribution or processing.
- **(k) Farms {§1.227}, fishing vessels**, establishments engaged in activities pertaining to **nuts**, etc.

# Examples of Compliance with Prevention Standards

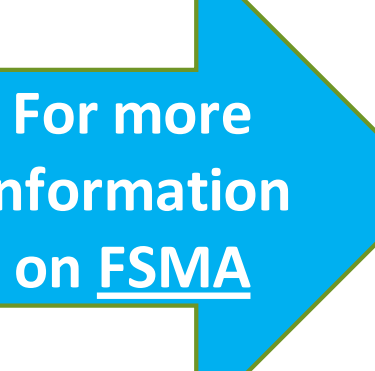
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- Current Good Manufacturing Practices (cGMPs)
- Sanitation
- Training for supervisors and employees
- Hazard Analysis and Risk-Based Preventative Controls
  - Food Safety Plan
  - Hazard analysis
  - Preventive controls (chemical, physical, biological)
  - Control monitoring, verification, validation
  - Recall contingency plan
- Supplier verification activities



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## How Do I ?

## License or start Food/Drink Business

## Agricultural Promotion and Protection

## Agency Divisions

## State Fair

## License or Start Dairy Business

## Home Processors

Nursery Dealer

## Weighmaster

## Process Review

Through its various divisions and programs, promotes high-quality and diverse products, fosters agricultural and safeguards the State's food supply, land and quality and growth of New York's agriculture industries.

## The Snapshot

le's land area, or more than 7 million acres, is farmland. Family farms producing some of the world's best food, New York State economy. New York ranks high among the major states, ranking in the top 10 in production of 30 different crops. New York is the largest producer of apples, snap beans and maple syrup. The dairy industry is the largest segment of the State's agriculture, with New York producing more than 1 billion pounds of milk in 1997.

[s to 1 NYCRR Part 127](#) (Golden Nematode)  
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## Human Foods Preventive Control Rule



The Human Food for Preventive Controls Rule sets forth new requirements and updates existing requirements for facilities that manufacture, process, pack, or hold human food.

### Human Food for Preventive Controls Rule New Requirements

The new requirements include maintaining and implementing a written food safety plan that includes:

- **Hazard Analysis:** The plan must identify and evaluate hazards for each type of food manufactured, processed, packed, or held at the facility.
- **Preventive Controls:** The plan must identify preventive controls that significantly minimize or prevent hazards. Preventive controls include process controls, food allergen controls, sanitation controls, and a recall plan.
- **\*\* Supplier Program (NEW):** The plan must establish and implement a risk-based supplier program for raw materials and ingredients for which the receiving facility identifies a significant hazard and the hazard is controlled by the supplier.
- **Monitoring Procedures:** The plan must document procedures to ascertain that preventive controls are consistently performed.
- **Corrective Actions:** The plan must identify steps to take if preventive controls are not adequately implemented, to minimize the likelihood of problems reoccurring, to evaluate the food for safety, and to block problem food from entering commerce.
- **Verification:** The plan must spell out verification activities and document that preventive controls are effective and consistently implemented.
- **\*\* Verification of Implementation and Effectiveness (NEW):** Verification measures must include product testing and environmental monitoring, as appropriate to the facility, the food, and the nature of the preventive control.

A facility is required to maintain a written food safety plan and to keep records of each element of the plan. The rule adds a supplier approval and verification program, as well as environmental monitoring and product testing, to the requirements of the food safety plan.

Only an individual qualified either through training or experience can write the facility's food safety plan. Food safety plans would be reassessed every three years, or more frequently if there are problems.

### Updated GMP Requirements

The Preventive Control Rule also updates Current Good Manufacturing Practice (cGMP) requirements. Updates include clarifications on protections against cross-contact of food by allergens, language changes, and deletion of certain provisions containing recommendations. Facilities that are exempt or subject to modified requirements in the new requirements for hazard analysis and preventive controls would generally be subject to cGMP requirements.

**AT A GLANCE:** For a quick overview of the Human Food Preventive Control Rule requirements click on the link below:



For more  
general  
information



Please note: Menu Items  
have been re-arranged.



How Do I ?	<b>Welcome to the New York State Department of Agriculture and Markets Website.</b> The Department, through its various divisions and programs, promotes New York agriculture and its high-quality and diverse products, fosters agricultural environmental stewardship, and safeguards the State's food supply, land and livestock to ensure the viability and growth of New York's agriculture industries.
Consumer Information	
Agricultural Promotion and Protection	For more information to learn more about the Department's divisions, the Department's website provides a variety of resources for farmers, producers and agricultural businesses. Click on the Information tab to easily locate farmers' markets and other establishments, among others.
Regulation	<b>Taste NY</b>
Agency Divisions	<b>Running a Farmers' Market</b>
Contact Us	<b>Farm to School</b>
State Fair	<b>Agricultural Districts</b>
	<b>Farmland Protection</b>
	<b>Urban Agriculture</b>
	<b>Emergency Preparedness</b>
	<b>Resources for New Farmers</b>
	<b>Resources for Food Businesses</b>
	<b>Programs to Help Farms and Businesses</b>
	<b>Funding Opportunities</b>




**New York State Industrial Hemp Research Initiative**  
[Learn More](#)



[Good Agricultural Practices](#)





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# Agriculture and Markets

Please note: Menu Items  
have been re-arranged.

[How Do I ?](#)

[Consumer Information](#)

[Agricultural Promotion  
and Protection](#)

[Regulation](#)

[Agency Divisions](#)

[Contact Us](#)

[State Fair](#)

## Resources for Food Businesses

[Industry Information](#) | [Training](#) | [Posters](#)

AS YOU BEGIN OR MAINTAIN YOUR FOOD BUSINESS IT IS IMPORTANT THAT YOU FOLLOW THE INFORMATION AND PROCESSES OUTLINED BELOW:

**Step 1 - License** - Licenses should be filed prior to start up and renewed at the frequency on the application form. Provide link to 'Start my food business section'.

↓

**Step 2 - Processes** - Having a cleaning, sanitation, maintenance, cross-contamination and pest control programs in place will ensure your business is compliant with the Food Safety rules. See 'Industry Information' for helpful links below.

↓

**Step 3 - Training** - Ensuring your employees are trained, are hygienic/clean and disease free while working is vital to the success of your business. See training section below.

↓

**Step 4 - Posters** - Hanging posters that remind your employees of the food safety rules is very helpful. See posters section below.

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### Industry Information

[New York State Food Labeling](#)

[Proper Use of Sanitary Gloves](#)

[Sanitizing Solutions](#)

[Sushi Preparation Guidelines](#)

[Water Activity Values](#)

[Water Emergency Procedures](#)

# Resources

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1. **NYS Dept. of Agriculture & Markets website:**  
<https://www.agriculture.ny.gov/FS/GENERAL/FSMA.HTML>
  - Access to fact sheets, food safety plan templates, PCQI course registration information, etc.
2. **FDA website:** <https://www.fda.gov/Food/GuidanceRegulation/FSMA/>
3. **NYS Dept. of Agriculture & Markets contacts within the *Division of Food Safety and Inspection*:**
  - John Luker: [John.Luker@agriculture.ny.gov](mailto:John.Luker@agriculture.ny.gov)
  - Erin Sawyer: [Erin.Sawyer@agriculture.ny.gov](mailto:Erin.Sawyer@agriculture.ny.gov)



# Questions ?